

UNCLASSIFIED

AD NUMBER
ADB263521
NEW LIMITATION CHANGE
TO Approved for public release, distribution unlimited
FROM Distribution authorized to U.S. Gov't. agencies only; Proprietary Info.; Aug 1999. Other requests shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott St., Fort Detrick, MD 21702-5012.
AUTHORITY
U.S. Army Medical Research and Materiel Command and Fort Detrick ltr., dtd October 17, 2001.

THIS PAGE IS UNCLASSIFIED

AD _____

Award Number: DAMD17-99-2-9005

TITLE: A Uniform Services Comprehensive Database and Tissue
Repository for the Study of Epidemiological, Detection,
Natural History and New Management Strategies for Prostate
Cancer

PRINCIPAL INVESTIGATOR: Isabelle A. Sesterhenn, M.D.

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation
Rockville, Maryland 20852

REPORT DATE: August 1999

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Distribution authorized to U.S. Government
agencies only (proprietary information, Aug 99). Other requests
for this document shall be referred to U.S. Army Medical Research
and Materiel Command, 504 Scott Street, Fort Detrick, Maryland
21702-5012.

The views, opinions and/or findings contained in this report are
those of the author(s) and should not be construed as an official
Department of the Army position, policy or decision unless so
designated by other documentation.

DMIC QUALITY INSPECTED 4

20010216 100

NOTICE

USING GOVERNMENT DRAWINGS, SPECIFICATIONS, OR OTHER DATA INCLUDED IN THIS DOCUMENT FOR ANY PURPOSE OTHER THAN GOVERNMENT PROCUREMENT DOES NOT IN ANY WAY OBLIGATE THE U.S. GOVERNMENT. THE FACT THAT THE GOVERNMENT FORMULATED OR SUPPLIED THE DRAWINGS, SPECIFICATIONS, OR OTHER DATA DOES NOT LICENSE THE HOLDER OR ANY OTHER PERSON OR CORPORATION; OR CONVEY ANY RIGHTS OR PERMISSION TO MANUFACTURE, USE, OR SELL ANY PATENTED INVENTION THAT MAY RELATE TO THEM.

LIMITED RIGHTS LEGEND

Award Number: DAMD17-99-2-9005

Organization: Henry M. Jackson Foundation

Location of Limited Rights Data (Pages):

Those portions of the technical data contained in this report marked as limited rights data shall not, without the written permission of the above contractor, be (a) released or disclosed outside the government, (b) used by the Government for manufacture or, in the case of computer software documentation, for preparing the same or similar computer software, or (c) used by a party other than the Government, except that the Government may release or disclose technical data to persons outside the Government, or permit the use of technical data by such persons, if (i) such release, disclosure, or use is necessary for emergency repair or overhaul or (ii) is a release or disclosure of technical data (other than detailed manufacturing or process data) to, or use of such data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes, provided in either case that such release, disclosure or use is made subject to a prohibition that the person to whom the data is released or disclosed may not further use, release or disclose such data, and the contractor or subcontractor or subcontractor asserting the restriction is notified of such release, disclosure or use. This legend, together with the indications of the portions of this data which are subject to such limitations, shall be included on any reproduction hereof which includes any part of the portions subject to such limitations.

THIS TECHNICAL REPORT HAS BEEN REVIEWED AND IS APPROVED FOR PUBLICATION.

N/A Single Charan Minna
01/20/01

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)**2. REPORT DATE**

August 1999

3. REPORT TYPE AND DATES COVERED

Fianl (15 Nov 98 - 14 Aug 99)

4. TITLE AND SUBTITLE

A Uniform Services Comprehensive Database and Tissue Repository for the Study of Epidemiological, Detection, Natural History and New Management Strategies for Prostate Cancer

3. AUTHOR(S)

Isabelle A. Sesterhenn, M.D.

5. FUNDING NUMBERS

DAMD17-99-2-9005

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Henry M. Jackson Foundation
Rockville, Maryland 20852

E-Mail: sesterhe@afip.osd.mil**8. PERFORMING ORGANIZATION
REPORT NUMBER****9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSORING / MONITORING
AGENCY REPORT NUMBER****11. SUPPLEMENTARY NOTES****12a. DISTRIBUTION / AVAILABILITY STATEMENT****12b. DISTRIBUTION CODE****13. ABSTRACT (Maximum 200 Words)**

The Tri-Service Project Working Group, under the direction of the US Army Medical Research and Development Command convened in the fall of 1997 and throughout early 1998 to develop an agenda for prostate cancer research. Members of the Tri-Service Project Working Group were composed of the US Army medical Research and Development Command, Armed Forces Institute of Pathology and various urologic military medical researchers from Army, Navy, and Air Force medical centers. The Director for Prostate Cancer Research, Congressionally Directed Medical Research Programs, US Army Medical Research and Development Command chaired the Tri-Service Project Working Group. The Tri-Service Project Working Group expressed a need for a centralized repository which would include sera, tissue and clinical data of prostate cancer patients which would serve as a national resource for prostate cancer research, and directed a scientific proposal be develop for submission to US Army Medical Research and Materiel Command for funding. The project was recommended for funding 22 September 1998 contingent upon resolution of the Peer and Programmatic reviews to be conducted in two phases. Phase I directed the hire of a study coordinator to assist the principal investigator in day-to-day management, and to develop and submit a revised proposal to address the weaknesses and deficiencies noted in peer and programmatic review. A revised proposal was submitted 1 June 1999 addressing the weaknesses and deficiencies noted in the peer and programmatic review. The project is currently waiting funding.

14. SUBJECT TERMS

Prostate Cancer

15. NUMBER OF PAGES

9

16. PRICE CODE**17. SECURITY CLASSIFICATION
OF REPORT**

Unclassified

**18. SECURITY CLASSIFICATION
OF THIS PAGE**

Unclassified

**19. SECURITY CLASSIFICATION
OF ABSTRACT**

Unclassified

20. LIMITATION OF ABSTRACT

Limited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

TABLE OF CONTENTS

A.	Front Cover.....	
B.	SF 298.....	
C.	Foreword	
D.	Table of Contents.....	4
E.	Introduction.....	5
F.	Body.....	6-8
G.	Conclusion.....	8

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

___ Where copyrighted material is quoted, permission has been obtained to use such material.

___ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

X Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

X In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

2 September 8. Feb 2022
PI - Signature Date

INTRODUCTION

The Tri-Service Project Working Group, under the direction of the US Army Medical Research and Development Command convened in the fall of 1997 and throughout early 1998 to develop an agenda for prostate cancer research. Members of the Tri-Service Project Working Group were composed of the US Army Medical Research and Development Command, Armed Forces Institute of Pathology and various urologic military medical researchers from Army, Navy, and Air Force medical centers. The Director for Prostate Cancer Research, Congressionally Directed Medical Research Programs, US Army Medical Research and Development Command chaired the Tri-Service Project Working Group.

The major purpose of the Tri-Service Project Working Group was to advance an agenda for military medical prostate cancer research. The Tri-Service Project Working Group first listed goal was to develop a comprehensive relational database on individuals diagnosed with prostate cancer. This database would link clinicians treating cases of prostate cancer, pathologists in military medical centers, and the Armed Forces Institute of Pathology (AFIP) as part of a Department of Defense (DoD) network of prostate cancer data. The program would be designed to facilitate rapid multidisciplinary sharing and collaboration among clinicians, pathologists, and researchers of data collected on prostate cancer cases seen in DoD medical treatment facilities. The database will help to provide data useful for development of proposals for research projects of the type described in the DoD Prostate Cancer Research Program. Activities of the project would include coordination of a bank of tissue and serum samples from patients with prostate cancer, linkage of samples in the tissue and serum bank with clinical patient data, development of an infrastructure for rapid sharing of treatment outcomes, linkage with all Prostate Specific Antigen (PSA) test results, and linkage to existing stored tissue and serum samples from the same individuals.

The Tri-Service Prostate Cancer relational database would combine in a single, highly accessible source, the results of pathology exams, clinical staging, demographic factors such as race, ethnicity and place of birth, medical history, and lifetime military occupational history. It would catalog and identify the location and status of all available stored biological materials and clinical data from the patients in a single comprehensive database. The Tri-Service Prostate Cancer relational database would be updated to include the results of all medical, scientific and career events related to the patient, including hospitalizations, surgery, treatment, survival and results of all testing performed on tissue samples, serum, or other biological materials. All data will be accessible to clinicians, pathologists, and researchers. In addition, all patient data would be made available to the patient's physicians. The database will serve as a central resource of cases for multiple satellite research protocols from military medical centers with particular emphasis on the testing of new hypotheses and innovative epidemiological research on prostate cancer. The Armed Forces Institute of Pathology was selected as the central repository site.

BODY

The Tri-Service Project Working Group expressed a need for a centralized repository which would include sera, tissue and clinical data of prostate cancer patients which would serve as a national resource for prostate cancer research, and directed a scientific proposal be developed for submission to US Army Medical Research and Materiel Command for funding.

The Tri-Service Project Working Group selected Colonel Nancy Dawson, MC, Hematology/Oncology Service, Walter Reed Army Medical Center, as the overall principal investigator for the project. The Henry M. Jackson Foundation was asked to join the Tri-Service Cancer Working Group to provide its administrative and management expertise in developing the technical proposal and managing the project. The following military sites were selected as participants to initiate this project:

Walter Reed Army Medical Center, Washington, D.C. (Army)
Malcolm Grow Medical Center, Andrews AFB, Maryland (USAF)
Madigan Army Medical Center, Tacoma, Washington (Army)
Naval Medical Center, San Diego, California (Navy)
Brooke Army Medical Center, Fort Sam Houston, Texas (Army)
Wright Patterson Medical Center, Wright Patterson AFB, Ohio (USAF)

The primary goal of this project was to establish a comprehensive serum and tissue repository utilizing the Armed Forces Institute of Pathology to archive all specimens and clinical data, and the Tri-Service network of military medical centers for patient recruitment for the study of the etiology of prostate cancer. The secondary goal of this project would be the incorporation of a demonstration project to illustrate the utility of the repository.

The Tri-Service Project Working Group agreed that the serum and tissue repository be conducted in two (2) phases. It was agreed that phase I should be the establishment of a Tri-Service Tissue and Serum repository as a resource for both military and non-military investigators. Phase II should be the incorporation of a demonstration project to illustrate the utility of the repository.

Phase One:

In phase one, the primary objective would be to establish a prostate cancer serum and tissue repository as a resource for both military and non-military investigators. Initially, the tissue will consist of radical prostatectomy and lymph nodes specimens removed for prostatic carcinoma, which will be processed according to a defined protocol. The histological analysis will have local and central review. The project would encompass the utilization of six (6) peripheral, geographically dispersed military sites encompassing all branches of the services which would ship serum, tissue samples, and clinical information to the Armed Forces Institute of Pathology for the archiving of the data and tissue

samples. Additionally, standardized data collection instruments will be used at the designated centers by clinical research personnel and physicians to collect comprehensive prospective and retrospective information from men with prostate cancer. For geographic and service diversity, these sites include:

Phase Two:

Phase II will be the incorporation of a demonstration project to illustrate the utility of the repository. The primary objective of phase two will be the establishment of a centralized database at the Armed Forces Institute of Pathology that would incorporate the tissue, serum and clinical data and demonstrating the utility of the repository.

Assuming the success of phases I and II, additional military sites will be expanded to include additional peripheral, geographically dispersed military sites encompassing all branches of the services which will ship serum, tissue samples and clinical data to the Armed Forces Institute of Pathology for the archiving of the data samples.

Chronological History:

15 December 1997 – The Tri-Service Project Working Group finalized decisions for a Tri-Service Database Repository and directed the writing of a scientific proposal to be submitted to US Army Medical Research and Materiel Command.

15 April 1998 – The proposal entitled, “ A Uniformed Services Comprehensive Database and Tissue Repository for the Study of Epidemiological, Detection, Natural History and New Management Strategies for Prostate Cancer” was submitted to US Army Medical Research and Materiel Command.

22 September 1998 – The proposal was recommend for funding, contingent upon resolution of the Peer and Programmatic reviews. US Army Medical Research and Materiel Command proposed to enter into a two-phase contract. During Phase I the Foundation was directed to hire a study coordinator to assist Dr. Dawson in day-to-day management and direction of the study. During Phase II the principal investigator would develop and submit a revised proposal to address the weaknesses and deficiencies noted in peer and programmatic review.

13 October 1998 – A revised budget and statement of work was submitted to US Army Medical Research and Materiel Command for Phase I.

12 November 1998 – A cooperative agreement for Phase I was signed between the Foundation and US Army Medical Research and Materiel Command in the amount of \$108,113.00.

February 1999 – Dr. Dawson announced her retirement from military service, and that she would no longer serve as principal investigator. Dr. Isabell A. Sesterhenn, Armed Forces Institute of Pathology was selected as the principal investigator to replace Dr. Dawson.

1 June 1999 – A revised proposal addressing the weaknesses and deficiencies noted in the peer and programmatic review was submitted to US Army Medical Research and Materiel Command.

9 September 1999 – The revised proposal was recommended for funding at a reduced budget pending submission /approval of required appendices. The programmatic review panel proposed to fund this project for one year at a reduced budget of up to \$300,000.

13 December 1999 – Additional guidance was received from US Army Medial Research Acquisition Activity regarding the submission of a revised budget. Up to \$250,000 was proposed to initiate collection of materials and up to \$50,000 was proposed to be utilized for consultation/outsourcing for the development and management of the database, forms, and work assignments.

31 January 2000 – A revised budget and Representations and Certifications packet was submitted to US Army Medical Research Acquisition Activity.

CONCLUSION:

Due to the ongoing nature of this contract, no conclusions have been reached at this time. We anticipate to be on contract by late February 2000 for the initial \$300,000. Due to the initial budget guidance of \$300,000, the following actions were necessary to meet the budget cap:

1. Elimination of Wright Patterson Medical Center, 74th Medical Group, Wright Patterson AFB, Ohio as a participating site in the study.
2. Defer purchasing equipment, blood/tissue collection supplies and office supplies for participating centers.
3. Defer overnight shipping contract for tissue/blood.
4. Defer hiring the histotechnician, data coordinator, and study coordinator.

Approximately, six months after receipt of funds, progress report will be submitted to US Army Medical Acquisition Activity. This progress report will be programmatically reviewed and pending the review, additional funds of up to \$600,000 may be awarded.



DEPARTMENT OF THE ARMY

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND AND FORT DETRICK
810 SCHRIEDER STREET, SUITE 218
FORT DETRICK, MARYLAND 21702-5000

*Rec'd
10/29/2001*

REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y)

17 Oct 01

MEMORANDUM FOR Administrator, Defense Technical Information
Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir,
VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for grants. Request the limited distribution statements for the Accession Document Numbers listed at enclosure be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by e-mail at judy.pawlus@det.amedd.army.mil.

FOR THE COMMANDER:

PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

Enclosure